CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED ADOPTION OF SECTION 100120 – MES STANDARDS RECORD KEEPING

HEARING DATE: None Scheduled.

SUBJECT MATTER OF PROPOSED REGULATIONS: MES Standards Record Keeping

SECTIONS AFFECTED: The proposed regulation adopts section 100120 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR ADOPTION:

SECTION 100120 – RECORD KEEPING:

Purpose:

This section requires grantee institutions to maintain described records that concern CIRM–funded research activities. The subdivisions of this section require a grantee institution to maintain records documenting pertinent review or notification requirements as required in Section 100070; record of all gametes, somatic cells, embryos or products of SCNT that have been donated, created or used so as to determine the provenance and disposition of such materials. The section also requires that the records be made available at CIRM's request.

Rationale:

This regulation is necessary to ensure compliance with requirements imposed on the CIRM to track the use of CIRM funds and to ensure compliance with applicable statutes and regulations. National Academy Guidelines (6.1) state that institutions should require documentation of the provenance of all human embryonic stem cell lines, whether the cells were imported into the institution or generated locally. Notice to the institution should include evidence of IRB–approval of the procurement process, evidence of and adherence to basic ethical and legal principles of procurement, as indicated in the recommendation. In the case of lines imported from another institution, it is recommended that documentation that these criteria were met at the time of derivation will suffice. This section ensures the integrity of the donation process is assured and that future use of particular stem cell lines and materials can comply with necessary provenance and derivation requirements.